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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,787	08/14/2001	Edward J. Noga	5051-551	9013
20792	7590	05/03/2004	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC			ZEMAN, ROBERT A	
PO BOX 37428			ART UNIT	PAPER NUMBER
RALEIGH, NC 27627			1645	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/929,787	NOGA ET AL.	
	<b>Examiner</b> Robert A. Zeman	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 12 February 2004.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-10 and 19 is/are pending in the application.
  - 4a) Of the above claim(s) 1-4, 10 and 19 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 5-9 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)               |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7-26-02</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of Group II in the paper filed on 2-12-2004 is acknowledged. The traversal is on the ground(s) that the inventions of Group II are related to the inventions of Group I as a process and products made by that process. This is not found persuasive because according to MPEP § 806.05(f), when inventions related as process of making and product made the inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process. In the instant case the peptides of Group I can be made synthetically.

The requirement is still deemed proper and is therefore made FINAL.

The amendment filed on 2-12-2004 is acknowledged. Claims 11-18 and 20-27 have been canceled. Claims 1-10 and 19 are pending. Claims 1-4, 10 and 19 have been withdrawn from consideration. Claims 5-9 are currently under examination.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP

§ 2172.01. The omitted steps are: method steps for detecting a peptide having antimicrobial activity in mast cells and method steps for isolating said peptide.

Claims 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is confusing. It is unclear how one measures the antimicrobial activity of a given peptide (step b) before said peptide has been isolated. Moreover, the instant claims are drawn to methods of isolating antimicrobial peptides but fail to recite any active steps that constitute said method.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-6 and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Robinette et al. (Cellular and Molecular Life Sciences Vo. 54, 1998, pages 467-475) in light of Abraham et al. (Infection and Immunity, Vol. 65, No. 9, pages 3501-3508).

The instant claims are drawn to methods of isolating antimicrobial peptides comprising providing mast cells where in said mast cells are optionally from either fish or mammals.

Robinette et al. disclose the isolation of antimicrobial polypeptides from the skin of channel catfish *Ictalurus punctatus*. Said methods included the extraction of skin samples, fractionation of the resulting extracts and the testing of said fractions for antimicrobial activity (see pages 468-471). While, Robinette et al. do not explicitly disclose the isolation of peptides from mast cells, said mast cells would be present in the skin samples used by Robinette et al. since mast cells are present in high concentrations in skin (see Abraham et al., page 3501 first and second paragraph).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Selsted et al. (WO 94/21672) in view of Abraham et al. (Infection and Immunity, Vol. 65, No. 9, pages 3501-3508).

The instant claims are drawn to methods of isolating antimicrobial peptides comprising providing mast cells where in said mast cells are optionally from mammals.

Selsted et al. disclose methods of isolating antimicrobial peptides from bovine neutrophils. Said methods included the extraction of skin samples, fractionation of the resulting extracts and the testing of said fractions for antimicrobial activity (see Examples I-VII). Selsted et al. differs from the instant invention in that they do not explicitly disclose the isolation of peptides from mast cells. Abraham et al. disclose the role mast cells play in infection and immunity. Specifically, they disclose that mast cells produce a number of antimicrobial polypeptides. Said peptides are contained in vacuoles and are involved in phagocytosis (see page 3504) or are excreted and act directly on the microbe (see page 3504). Consequently, it would have been obvious to one of ordinary skill in the art to utilize the methods disclosed by Selsted et al. to isolate antimicrobial polypeptides from mast cells. One would have had a high expectation of success since neutrophils and mast cells both are phagocytic cells <sup>with</sup> multiple features (see Table 2 of Abraham et al.). Therefore, the use of mast cells in the methods of Selsted et al. merely constitute an obvious variation of the disclosed invention.

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Zeman  
April 27, 2004

*Lynette R. F. Smith*  
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